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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,494	04/28/2000	Bent Karsten Jakobsen	102286.413	3480

7590 12/09/2002
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EXAMINER

SCHWADRON, RONALD B

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/09/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/560,494

Applicant(s)
Jakobsen et al.

Examiner
Ron Schwadron, Ph.D.

Art Unit
1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 6-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

1. Applicant's election with traverse of Group I claims 1-5 in Paper No. 19 is acknowledged. The traversal is on the ground(s) that are stated in said paper. This is not found persuasive because of the following reasons. Regarding applicants comments about serious burden, the M.P.E.P. § 803 states that: "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The restriction requirement enunciated in the previous Office Action meets this criterion and therefore establishes that serious burden is placed upon the Examiner by the search of additional Groups.

The requirement is still deemed proper and is therefore made FINAL.

2. It is noted that a preliminary amendment filed with the instant application has been entered which adds claims 20-23 drawn to a complex of the protein of claim 10,11,12 or 13. These claims have been added to Group II.

3. Claims 6-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions, the requirement having been traversed in Paper No. 19.

4. Claims 1-5 are under consideration. Claims 3 and 5 were amended in the preliminary amendment filed with the instant application.

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because it does not identify the mailing or post office address of each inventor. While the instant declarations disclose a residence disclosing a city and country, a mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address (eg. street address). The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

6. All sequences disclosed in the specification are required to be identified with the

appropriate SEQ. ID. Number. The sequences disclosed in the specification, page 6, lines 17 and 22 are not identified with the appropriate SEQ. ID. Number.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the . . . claimed subject matter", *Vas-Cath, Inc. V. Mahurkar*, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of claimed invention.

The instant claims recite use of a soluble form of CD8. Claims 1,3-5 would encompass use of soluble CD8 derived from any mammal. There are thousands of species of mammals and the only two native CD8 molecules disclosed in the specification are human and mouse (wherein amino acid sequences have been provided for said molecules). Regarding the term CD8, it appears that said term would encompass a vast array of undefined mutants, allelic variants and other undisclosed CD8 molecules (eg. see claim 3). Regarding claim 2 which recites use of human CD8 (and claims 1,3-5 which encompass use of human CD8), it appears that said term would encompass countless mutants, allelic variants and other undisclosed CD8 molecules (eg. see claim 3). The specification provides description of the native amino acid sequence of a single human CD8. Thus, the written description provided in the specification is not commensurate with the scope of the claimed inventions. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the

invention claimed herein. See *The Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In *University of California v. Eli Lilly and Co.*, 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, *id.* at 1240. In the instant case, the specification has disclosed a single form of human or mouse CD8, whilst the claims encompass use of mammalian CD8 per se or human mutants and allelic variants of CD8. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", *Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd.*, 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606.

9. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in the recitation of "substantial part of the native CD8" because it is unclear what this means or encompasses. It is unclear as to what constitutes a "substantial part" of the native CD8. This term has no art recognized meaning and it is not defined in the

specification.

10. The specification defines "membrane proximal stalk region of CD8" as amino acids 116-160 of CD α .

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Tykocinski et al. (5242687) or Tykocinski et al. (5601828) or Tykocinski et al. (5623056).

The Tykocinski et al. patents have identical disclosures. The instant rejection will refer to the subject matter as per found in 5242687. Tykocinski et al. teach soluble human CD8 containing amino acids 1-160 of CD8 (see column 5, last paragraph). The CD8 immunoglobulin domain is found in amino acids 1-115 of CD8 (see specification, page 10). Tykocinski et al. define CD8 as encompassing CD8 α (see column 5, second paragraph). Said CD8 is soluble because it contains only the extracellular domain of CD8. Tykocinski et al. teach use of soluble CD8 (see abstract). Tykocinski et al. teach that target cells contacted with CD8 inhibit T cell alloreactivity (see column 15, second paragraph). Tykocinski et al. teach CD8 multimers (see column 10, penultimate paragraph).

13. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Jameson et al. (WO 96/22106).

Jameson et al. teach soluble peptides which contain specific CD8 derived peptides and also include other CD8 amino acids (see page 16, second paragraph). Said peptides contain a substantial portion of the CD8 immunoglobulin domain (eg. they contain peptides derived from fragments of amino acids 1-115 of CD8, see page 16, second paragraph). The peptides inhibit T cell responses and can be used to treat graft rejection (see abstract) wherein the administered peptide would inherently contact the target cell in vivo.

14. No claim is allowed.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group ~~180~~ receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600



Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644